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| 09/976,238      | 10/12/2001  | David A. Basiji      | BIOL0029            | 9708             |

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EXAMINER

TRAN, MY CHAU T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1639

DATE MAILED: 04/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,238

Applicant(s)

BASIJI ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 13-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I (Claims 1-2 and 8-12) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Groups of I-VIII are related to the subject matter of optically discriminable reporters and therefore all claims of these groups should be classified and examined together.

This is not found persuasive because in view of the discussion in paragraphs 2 of the 11/07/02 Office Action in which the examiner clearly describes patentable distinctions among the various inventions. Applicants have not addressed any errors in the reasoning set forth by the examiner in paragraphs 2-3.

Additionally, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example a patentability determination for Group III would involve a determination of the patentability of the method step of combining a plurality of singly labeled microparticles together to generate an aggregate reporter while a patentability determination for Group V would involve a consideration of the patentability of the method step of pooling contents from each reaction vessel to form a common pool. These considerations are very different in nature. Each of these different methods for each group has different methods steps that are different in requiring different reagents and/or producing different results. Additionally, it is submitted that the inventions of Groups of I-VIII have

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acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each group.

For these reasons, the restriction requirement is deemed to be proper and is therefore made **FINAL**.

2. Claims 3-7 and 13-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

***Priority***

3. Receipt is acknowledged of a foreign application (Application # 0019744.2, England), which has been placed of record in the file. But it is unclear if applicant is claiming priority to this foreign application. However, it is noted that this foreign application the inventor (e.g. Fermentas, AB) differs from that of the application (e.g. David A. Basiji and William E. Ortyn).

4. Claims 1-2, and 8-12 are treated on the merit in this Office Action.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-2, and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1 and 8 recite the reporter is attached to the carrier by a physical attachment.

Clarification is requested because it is unclear as to the distinction between a physical attachment (e.g. painting) and a chemical attachment.

b) The phrase “predetermined unique combination” of claims 1 and 8 is vague and indefinite because it is unclear what constitutes the metes and bounds of “unique combination” (e.g. color combination, structural combination, or type of product produced such as a signal).

c) The term “predetermined” is a relative term, which renders the claim indefinite. The term “predetermined” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

d) It is unclear as to what type of “library” (e.g. a library of bead or a library of chemical compounds) is being claimed in both claims 1 and 8. The presently claimed invention would encompass a library of beads.

e) It is unclear in claim 2 as to what is being claimed as the “optical distinctness” of the “carrier” since claim 1 for which claim 2 depend the “optical distinctness” is claimed as the “reporter”. It is unclear if there is a distinction between the “reporter” and “the carrier” and how claim 2 would further limit claim 1.

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f) It is unclear as to “optical” property of the “optically distinct carriers” of claims 2 and

9. The “optical” property of the carrier could refer to the structure of the carrier (e.g. fluorescent or chemiluminescence characteristics) or the “coating” of the carrier (e.g. color beads or labeled beads).

7. Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The type of detection use to distinguish the combination of reporter and carrier. That is detection base on intensity would have different reagents and mode of operations (e.g. type device use) than detection base on size or shape (e.g. the characteristic of the carrier). Further, intensity would encompass characteristics such as fluorescent, chemiluminescence, or color combination, which have different effects and mode of operations.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Patent 5,922,617).

*“The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of*

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*optically distinct reporter, a plurality of carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a reporter and does not contains a mixture of different optically distinct reporter labeled carriers. The reporter is attached to the carrier a physical attachment or a chemical attachment. ”*

Wang et al. disclosed a method of preparing a microarray (library) that comprise of beads (carriers) and bound components wherein the bound components comprise of a label such as a fluorescent label (optical reporters) (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). The bound component can be directly bound (chemical attachment) or indirectly bound (physical attachment) to the beads (referring to the attaching step) (col. 5, lines 60-64; col. 3, lines 17-30). The arrays employ individual segments (reaction vessels) wherein each segments contains different particles carrying bound components (referring to claims 1d) and 2) (col. 6, lines 21-32; col. 14, lines 35-59). Therefore, the method of Wang et al. anticipates the presently claimed invention.

10. Claims 1, 8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (US Patent 5,708,153).

*“The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of optically distinct reporter, a plurality of (optically distinct) carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a reporter. The reporter is attached to the carrier a physical attachment or a chemical attachment. ”*

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Dower et al. disclosed a method of producing a synthetic oligomer library that incorporates identifier tags (col. 7, lines 57-67 to col. 8, lines 1-7; fig. 2). The method comprises the following method steps: 1) apportioning the supports (carrier) among a plurality of reaction vessels; 2) exposing the supports in each reaction vessels to a first oligomer monomer and to a first identifier tag (reporter) monomer; 3) pooling the supports; 4) apportioning the supports among a plurality of reaction vessels; 5) exposing the supports to a second oligomer monomer and to a second identifier tag monomer. The identifier tag may be attached by mean of a linker (physical or chemical attachment) that has an appropriate functional group at each end, one for the attachment to the support and the other for the attachment to the identifier tag (referring to the attaching step for both claims 1 and 8) (col. 7, lines 50-54). The identifier tag may be any recognizable feature such as microscopically distinguishable in shape, size, color, or optical density (referring to step (c) for both claims 1 and 8) (col. 4, lines 24-36). The solid support may be any shape that is not homogenous in size, shape, or composition (col. 8, lines 35-44). Two or more distinctly different populations of solid support may be used (referring to claim 8 (a)). Therefore, the method of Dower et al. anticipates the presently claimed invention.

11. Claims 8-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarling et al. (US Patent 5,674,698).

*"The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of optically distinct reporter, a plurality of optically distinct carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a*



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*reporter. No reaction vessel contains a mixture of different optically distinct reporter labeled carriers. The reporter is attached to the carrier by a physical attachment or a chemical attachment. The optically distinct reporter and the optically distinct carriers are distinguishable based on intensity."*

Zarling et al. disclosed a method of providing a compositions (library) comprising fluorescent organic dye (reporter) attached to an inorganic up-converting phosphor (carrier) (col. 8, lines 8-22). The method comprise of the fluorescent organic dye maybe adsorbed to the inorganic up-converting phosphor crystal and/or attached to a coated inorganic up-converting phosphor crystal (col. 18, lines 55-67 to col. 19, lines 1-3; col. 19, lines 62-66; fig. 9). Several phosphors/dyes are selected which have overlapping absorption bands which allows simultaneous excitation at one wavelength, but which vary in emission characteristics such that each probe-label species is endowed with a distinguishable fluorescent "fingerprint" (col. 7, lines 30-35). The compositions are contains in wells (col. 9, lines 54-55; fig. 28). Therefore, the method of Zarling et al. anticipates the presently claimed invention.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617) in view of Furka (WO 93/24517).

*"The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of optically distinct reporter, a plurality of optically distinct carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a reporter and does not contains a mixture of different optically distinct reporter labeled carriers. The reporter is attached to the carrier by a physical attachment and a chemical attachment. The optically distinct reporter and the optically distinct carriers are distinguishable based on intensity, size, or shape."*

Wang et al. disclosed a method of preparing a microarray (library) that comprise of beads (carriers) and bound components wherein the bound components comprise of a label such as a fluorescent label (optical reporters) (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). The bound component can be directly bound (chemical attachment) or indirectly bound (physical attachment) to the beads (col. 5, lines 60-64; col. 3, lines 17-30). The arrays employ individual

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segments (reaction vessels) wherein each segments contains different particles carrying bound components (optically distinct reporter labeled carrier) (col. 6, lines 21-32; col. 14, lines 35-59).

The method of Wang et al. does not expressly disclose that the beads are optically distinct.

Furka disclosed a method synthesizing a sub-kit of peptide library bound to color and/or fluorescent support where the color, or the fluorescence, or the size or the specific gravity of the beads or combinations of these characteristics are assigned (pg. 10, lines 29-33). The support bound mixture can be screened without the use of expensive sequenators (pg. 19, lines 15-16).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include beads are optically distinct as taught by Furka in the method of Wang et al. One of ordinary skill in the art would have been motivated to include beads are optically distinct in the method of Wang et al. for the advantage of providing a support bound mixture can be screened without the use of expensive sequenators. Since both Wang et al. and Furka disclose a method of preparing a library of beads with bound components such as peptide (Wang: col. 6, lines 3-5 and col. 5, lines 7-9; Furka: pg. 10, lines 29-33).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct  
April 4, 2003

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**